and Research (CBER), and the Director and Deputy Directors of the Office of Blood Research and Review (OBRR), the Office of Vaccines Research and Review (OVRR), and the Office of Therapeutics Research and Review (OTRR), CBER.

(b) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device first intended for commercial distribution after May 28, 1976, under section 513 (f)(1)(A) of the act (21 U.S.C. 360c(f)(1)(A)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, and the Director, Deputy Directors, Division and Deputy Division Directors, Associate Division Directors, Branch Chiefs, and Chief, Premarket Notification Section, ODE, CDRH.

(2) The Director and Deputy Directors, CBER, and the Directors and Deputy Directors of the OBRR, OVRR, and OTRR, CBER.

(c) The following officials are authorized to make determinations and issue orders classifying devices under section 513(f)(2)(b):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Directors, ODE, CDRH.

(3) The Director and Deputy Directors, CBER, and the Directors and Deputy Directors of the OBRR, OVRR, and OTRR, CBER.

(d) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, and the Director and Deputy Directors, CBER, and the Directors and Deputy Directors of the OBRR, OVRR, and OTRR, CBER, are authorized to issue FEDERAL REGISTER notices under section 513(f)(2)(C) of the act (21 U.S.C. 360c(f)(2)(C)) announcing classification of devices under section 513(f)(2)(B) of the act (21 U.S.C. 360c(f)(2)(B)).

(e) These officials may not further redelegate those authorities.

§ 5.406 Notification to sponsors of deficiencies in petitions for reclassification of medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to notify sponsors of deficiencies in petitions for reclassification of medical devices submitted under sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f) and 360j(l)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors of the Office of Blood Research and Review, Office of Vaccines Research and Review, and Office of Therapeutics Research and Review, CBER.

(b) These officials may not further redelegate this authority.

§ 5.407 Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, declare as complete or incomplete, or revoke product development protocols for medical devices submitted under section 515(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(f)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), the Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH, and the Division Directors, ODE, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR),

and Office of Therapeutics Research and Review (OTRR), CBER.

(b)(1) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, or withdraw approval of applications for premarket approval for medical devices submitted under sections 515 and 520(l) of the act (21 U.S.C. 360e and 360j(l)):

(i) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, the Director and Deputy Directors, ODE, CDRH, and the Division Directors, ODE, CDRH.

(ii) The Director and Deputy Directors, CBER, and the Directors and Deputy Directors, OBRR, OVRR, and OTRR, CBER.

(2) For medical devices assigned to their respective division, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of supplemental premarket applications.

(c) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, for medical devices assigned to their organization, are authorized to issue notices to announce the approval, disapproval, or withdrawal of approval of a device, and to make publicly available a detailed summary of the information on which the decision was based, under sections 515(d), (e), and (g) and 520(h)(1) of the act (21 U.S.C. (d), (e), and (g) and 360j(h)(1)).

(d) These officials may not further redelegate these authorities.

§ 5.408 Determinations concerning the type of valid scientific evidence submitted in a premarket approval application.

(a) The following officials are authorized to make determinations under section 513(a)(3)(D) of the act (21 U.S.C. 360c(a)(3)(D)) concerning the type of valid scientific evidence to be submitted in a premarket approval application that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person:

(i) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(ii) The Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(iii) The Director, Program Operations Staff, ODE, CDRH.

(iv) For devices assigned to their respective Divisions: the Division Directors and Deputy Division Directors, ODE, CDRH.

(b) These officials may may not further redelegate this authority.

§ 5.409 Determinations that medical devices present unreasonable risk of substantial harm.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to determine that medical devices present an unreasonable risk of substantial harm to the public health, and to order adequate notification thereof, under section 518(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(a)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance and Biologics Quality, CBER.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

(b) These officials may not further redelegate this authority.

§ 5.410 Orders to repair or replace, or make refunds for, medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to order repair or replacement of, or refund for, medical devices under section 518(b) and (c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(b) and (c)):

(1) The Director and Deputy Directors for Science and for Regulations